REMARKS

I. Interview Summary

The undersigned Attorney wishes to thank the Examiner for the courtesy of the telephonic interview that occurred on 3 September 2003 as summarized in the Interview Summary , mailed 4 September 2003.

II. Claim Amendments

The claims have been amended to clarify that the dosage form of claim 1, and the claims dependent either directly or indirectly thereon, consists essentially of two active ingredients: (1) a H+,K+-ATPase inhibitor, and (2) a gastric antisecretory prostaglandin.

Claim 5, now canceled, provided that the dosage form of claim 1 further comprised a calcium channel blocking agent. However, in view of the cancellation of claim 5, it is now clear that the dosage form of claim 1 is characterized by the presence of the two recited active ingredients. Accordingly, the statement appearing at page 2 of the Advisory Action, i.e., "[t]he presence of claim 5 support's the examiner's position that additional ingredients may be present in the formulation", is no longer correct.

In contrast to claim 1, the dosage form of independent claim 40 is characterized by the presence of three active ingredients: (1) a H+,K+-ATPase inhibitor, (2) a gastric antisecretory prostaglandin, i.e., the same two ingredients as the dosage form of claim 1, and (3) a calcium channel blocker. In this regard, the Examiner's attention is also directed to claim 35 which claims a combination of the same actives (1), (2) and (3).

In addition to the cancellation of claim 5, the dependency of claims 2-4, 9-11, 31 and 32 has been amended. Support for amended claims 2 and 3 is provided by the specification at page 4, lines 19-25 and Example 11 at page 43.

Applicants submit that no new matter has been introduced by any of the claim amendments.

III. Claim Rejections – 35 U.S.C. §112

Claim 30 was rejected in the final Office Action under 35 U.S.C. §112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

Specifically, claim 30 was alleged to be indefinite in the use of the phrase "antisecretory prostaglandin analogue are coating layered with an extended release layer". Clarification was requested.

Claim 30 defines the embodiment wherein a coating layer is applied to the surface of the pellets comprising the gastric antisecretory prostaglandin analogue to provide an extended release profile. Support is provided by the paragraph bridging pages 7-8 of the specification. The application of such an extended release layer is well within the knowledge and skill of the person of ordinary skill in the art. Accordingly, Applicants respectfully submit that claim 30 is not indefinite within the meaning of 35 U.S.C. §112, second paragraph.

Withdrawal of the §112 rejection is requested.

IV. Claim Rejections – 35 U.S.C. §103

In the final Office Action claims 1-4, 11-27, 35, 38 and 39 were rejected under 35 U.S.C. §103(a) for alleged obviousness in view of US 6,365,184 to Depui et al. ("Depui") in combination with US 6,387,410 to Woolfe et al. ("Woolfe"). In support of the rejection, the Examiner relies on *In re De Lajarte*, 143 U.S.P.Q. 256 (CCPA 1964). Briefly, the Examiner alleged that Applicants have not meet their burden of showing the basic and novel characteristics of the claimed invention. The Examiner also alleged that the specification suggests the use of NSAIDs, or other gastrointestinal agents, in combinations with the claimed invention.

For all of the following reasons, Applicants respectfully disagree with the Examiner's interpretation of the cited case law and specification. Accordingly, the prior art rejections of record are improper and should be withdrawn.

1. There is no §102 rejection; *a fortiori*, Applicants have shown the ***basic or novel*** characteristics of the invention.

The rejected claims recite the transition expression "consisting essentially of". By definition, the phrase "consisting essentially of" excludes additional unspecified ingredients which would affect the ***basic or novel*** characteristics of the invention defined in the balance of the claim. By the mere fact that the claims are not rejected under any section of 35 U.S.C. §102 for lack of novelty, Applicants have met the burden of showing the ***basic or novel*** characteristics of the claimed invention.

The rejection of the claims under 35 U.S.C. §103 for alleged obviousness in view of the cited combination of references is an irrefutable acknowledgement that the claimed invention is ***novel***. The combination of Depui and Woolfe would not result in the claimed invention.

Thus, the patentable feature of the claim 1 is the combination of an ATP-ase inhibitor and prostaglandin in a single dosage form. Claim 40 similarly contains the transition expression "consisting essentially of". However, the patentable feature of claim 40 is the combination of the ATP-ase inhibitor, prostaglandin and calcium channel blocking agent in a single dosage form. Therefore, the claimed invention as defined by claim 1 and claim 40 excludes ingredients such as NSAIDs.

The Examiner relies on the *De Lajarte* decision in support of the proposition that Applicants have the burden of showing that the introduction of additional components, e.g., NSAIDs, excluded by the recitation of "consisting essentially of" would materially change the characteristics of the claimed invention. It is worth repeating that the claims are not rejected under any section of 35 U.S.C. §102 for lack of novelty. Therefore, Applicants have met the burden of showing the ***basic or novel*** characteristic of the claimed invention. Accordingly, pursuant to the *De Lajarte* decision, Applicants have also met their burden of showing a material change.

In this regard, the Examiner's attention is directed to *De Lajarte* at page 259 where the Court stated that the Appellant, having shown that the claimed invention had basic and novel properties, had also met the burden of showing that the introduction of additional components excluded by the recitation of "consisting essentially of" would materially change the characteristics of the claimed invention. In *De Lajarte*, the Court reversed the decision of the Board of Appeals affirming the rejection of the claims.

2. The specification does not disclose or suggest that the claimed dosage forms may also include a NSAID.

Contrary to the Examiner's allegation, the specification does not disclose or suggest that the claimed dosage forms may also include a NSAID. Rather, the disclosure appearing at page 20, lines 19-21, describes an optional therapy including the administration of the claimed dosage form "***in combination with other dosage forms***" comprising a calcium channel blocking agent, an NSAID or other antiulcerative agents. Thus, by the expression "other dosage forms", the only reasonable interpretation of the disclosure at page 20, lines 19-21, is the ***separate administration*** of the claimed dosage form and a second dosage form comprising a calcium channel blocking agent, an NSAID or other antiulcerative agent. This point is correctly stated in the Interview Summary.

However, as evidenced by the disclosure appearing at page 20, lines 7-10, the claimed invention also includes the combination of a H^+,K^+-ATPase inhibitor, prostaglandin and calcium channel blocking agent ***in a single dosage form.*** Further support for this specific embodiment is provided by the disclosure appearing at page 4, lines 10-13, and Example 3 at page 26.

In summary, Applicants submit that the rejection of claims 1-4, 11-27, 35, 38 and 39 under 35 U.S.C. §103(a) for alleged obviousness in Depui in combination with Woolfe is improper:

- the claims are not rejected under 35 U.S.C. §102; *a fortiori*, Applicants have shown the ***basic or novel*** characteristics of the invention;
- the Examiner has cited *De Lajarte* which supports the proposition that Applicants, having shown the ***basic or novel*** characteristics of the claimed invention, have met the burden of showing that the introduction of additional components excluded by the recitation of

"consisting essentially of" would materially change the characteristics of the claimed invention; and

- the combination of Depui and Woolfe would not result in the claimed invention.

Withdrawal of the §103 rejection is requested.

V. Claim Rejections – 35 U.S.C. §103

Claims 1-4, 11-27, 35, 38 and 39 were rejected under 35 U.S.C. §103(a) in the final Office Action for alleged obviousness in view of Akira Tari et al. ("Digestive Diseases and Sciences, Vol. 42) ("Tari") in combination with Depui. Tari does not disclose an oral dosage form of the combination omeprazole-enprostil. Accordingly, the Examiner relies on Depui for a disclosure of an oral dosage form comprising a proton pump inhibitor and a NSAID. For the reasons set forth in Section IV, above, the combination of Tari and Depui does not suggest the claimed invention which excludes additional unspecified ingredients such as NSAIDs which are required by Depui.

Withdrawal of the §103 rejection is requested.

V. Claim Rejections – 35 U.S.C. §103

In the final Office Action, claims 5-10, 31, 32 and 40 were rejected under 35 U.S.C. §103(a) for alleged obviousness in view of the combination of Depui, Woolfe and US 5,582,837 to Shell ("Shell"). Shell is relied upon for its alleged disclosure of a dosage form containing a calcium channel blocker for the treatment of gastric diseases.

As noted by the Examiner, the expected result would be a single dosage form comprising a combination of a proton pump inhibitor, NSAID, calcium channel blocker and prostaglandin.

However, the claimed invention as defined by the independent claims 1 and 40 excludes a NSAID. Therefore, the combination of Depui, Woolfe and Shell docs not suggest the claimed invention.

Withdrawal of the §103 rejection is requested.

CONCLUSION

Applicants respectfully submit that the claims are in condition for allowance, which action is earnestly solicited.

Authorization is hereby given to charge any additional fee required in connection with the communication to Deposit Account No. 23-1703.

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Respectfully submitted,

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Attachments: RCE (PTO/SB/30) and Fee Transmittal (PTO/SB17)